K022357

SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

a. **Date Prepared:** July 17, 2002

OCT 16 2002

b. **Contact Person**

George J. Prendergast
Regulatory Affairs Specialist II
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

c. **Trade Name**

Transend™ 300 ES Guidewire

Transend™ 300 Floppy Guidewire

d. **Common Name**

Catheter Guidewire

e. **Classification Name**

Catheter Guidewire (21 CFR Section 870.1330)

f. **Identification of Predicate Devices**

Number	Description	Clearance Date
K950069	Dasher™ - 14 Guidewire	12 April 1995
K950113	ChoICE™ Extra Support Guidewire ChoICE™ Floppy Guidewire	31 March 1995

g. Device Description

The *Transend™300 ES Guidewire* and *Transend™ 300 Floppy Guidewire* are intended for general intravascular use, including the neuro and peripheral vasculature. The 300cm length allows exchange of therapeutic devices without the use of other exchange devices, i.e. extension wires. The *Transend™300 ES Guidewire* and *Transend™ 300 Floppy Guidewire* have a nominal diameter of 0.014".

All device materials, manufacturing processes and product dimensions are identical to the Boston Scientific Scimed ChoICE™ ES 300cm exchange guidewire and the ChoICE™ 300cm Floppy exchange guidewire.

h. Intended Use

The *Transend™300 ES Guidewire* and *Transend™ 300 Floppy Guidewire* Indications For Use are as follows:

> The *Transend 300 ES Guidewire and Transend 300 Floppy Guidewire* are intended for general intravascular use, including the neuro and peripheral vasculature. The guidewires can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. These devices are not intended for use in coronary arteries. A torque device (pin vise) is included with the guidewires to facilitate directional manipulation of the guidewires.

i. **Product Feature Comparison**

Feature	FasDasher™ – 14 Guidewire Predicate device	Transend™ 300 ES Guidewire Transend™ 300 Floppy Guidewire Subject devices	ChoICE™ PTCA Exchange Guidewire ChoICE™ PTCA Exchange Guidewire Predicate devices
Intended Use	FasDasher-14 Guidewire is intended to assist delivery of catheters to selected vascular sites (neuro peripheral and coronary vasculature).	The Transend 300 ES Guidewire and Transend 300 Floppy Guidewire are intended for general intravascular use, including the neuro and peripheral vasculature. These devices are not intended for use in coronary arteries.	The ChoICE ES 300cm Exchange Guidewire ChoICE Floppy 300cm Exchange Guidewire are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA. The ChoICE guidewires are not intended for use in the cerebral vasculature.
Design: Length Distal Outiside Diameter	 195cm 0.014" minimum	 300cm 0.014" minimum	 300cm 0.014" minimum
Materials	Predominately stainless steel, platinum, polytetrafluoroethylene, polyurethane, lubricious coating	Predominately stainless steel, platinum, polytetrafluoroethylene, polyurethane, lubricious coating	Predominately stainless steel, platinum, polytetrafluoroethylene, polyurethane, lubricious coating

j. Comparison of Technological Characteristics

The *Transend™300 ES Guidewire* and *Transend™ 300 Floppy Guidewire* are substantially equivalent to the predicate devices in terms of functionality, intended use, design, materials, method of operation, size, length, sterilization methods, packaging, biocompatibility, and labeling.

k. Testing

In vitro performance testing of the *Transend 300 ES Guidewire* and the *Transend 300 Floppy Guidewire* included particle analysis, friction testing, angular rotation, tip buckling, and tip stiffness to gain clearance for a neurovascular and peripheral indications.

Biocompatibility testing was verified according to ISO-10993, *Biological Evaluation of Medical Devices*. Test results confirm biocompatibility of the *Transend 300 ES Guidewire* and the *Transend 300 Floppy Guidewire.*

All testing indicates that the devices are safe and perform according to their intended use.

l. Summary of Substantial Equivalence

Boston Scientific Target's determination of substantial equivalence to Boston Scientific Scimed's ChoICE™ Extra Support Guidewire and ChoICE™ Floppy Guidewire and Boston Scientific Target's FasDasher™- 14 Guidewire as predicate devices is based on the following.

The subject guidewires are substantially equivalent to the FasDasher-14 Guidewire with respect to the following:

- size
- intended use
- labeling
- biocompatibility
- packaging
- functionality
- method of operation

The subject guidewires are substantially equivalent to the Scimed's ChoICE™ Extra Support Guidewire and ChoICE™ Floppy Guidewire with respect to the following:

- materials
- size
- length
- labeling
- packaging
- sterilization methods
- functionality
- design
- method of operation
- biocompatibility

Based on the above information provided in this submission, Boston Scientific Target's *Transend™ 300 ES Guidewire* and *Transend™ 300 Floppy Guidewire* are substantially equivalent to Boston Scientific Target's FasDasher ™-14 Guidewire and Boston Scientific Scimed's ChoICE Extra Support Guidewire and ChoICE Floppy Guidewire.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2002

Boston Scientific Target
c/o Mr. George J. Prendergast
47900 Bayside Parkway
Fremont, CA 94538

Re: K022357
Transend™ 300 ES Guidewire and Transend™ 300 Floppy Guidewire
Regulation Number: 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: July 17, 2002
Received: July 19, 2002

Dear Mr. Prendergast:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

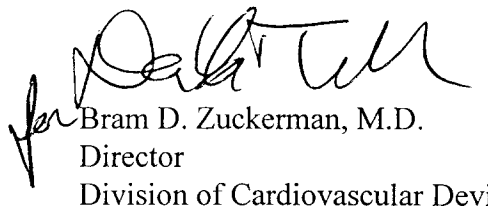
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Boston Scientific
TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: K022357

Device Name: ***Transend™ 300 ES Guidewire*** and ***Transend™ 300 Floppy Guidewire***

Indications for Use:

The *Transend™ 300 ES Guidewire and Transend™ 300 Floppy Guidewire* are intended for general intravascular use, including the neuro and peripheral vasculature. The guidewires can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. These devices are not intended for use in coronary arteries. A torque device (pin vise) is included to facilitate directional manipulation of the guidewires.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over The Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022357